In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: June 23, 2025

ASHLEY T. HUNSUCKER,	*	
Petitioner,	*	No. 18-821V
v.	*	Special Master Young
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Nancy Routh Myers, Turning Point Litigation, Greensboro, NC, for Petitioner.
Tyler King, U.S. Department of Justice, Washington, DC, for Respondent.

RULING ON ENTITLEMENT[1]

On June 11, 2018, Ashley T. Hunsucker ("Petitioner") filed a petition in the National Vaccine Injury Compensation Program (the Program"),[2] alleging that as the result of receiving an influenza ("flu") vaccine on October 5, 2015, she suffered small fiber neuropathy ("SFN"). Pet., ECF No. 1.

After carefully analyzing and weighing all the evidence and testimony presented in this case in accordance with the applicable legal standards,[3] I find that Petitioner has provided

[1] Because this Ruling contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the Ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[2] National Childhood Vaccine Injury Act of 1986, Pub L. No. 99-660, 100 Stat. 3755 ("the Vaccine Act" or "Act"). Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2018).

[3] While I have reviewed all of the information filed in this case, only those filings and records that are most relevant to the Ruling will be discussed. *Moriarty v. Sec'y of Health & Hum. Servs.*, 844 F.3d 1322, 1328 (Fed. Cir. 2016) ("We generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision.") (citation omitted); *see also Paterek v. Sec'y of Health & Hum. Servs.*, 527 F. App'x 875, 884 (Fed. Cir. 2013) ("Finding

preponderant evidence that the flu vaccine she received on October 5, 2015, caused her to suffer from SFN. Accordingly, Petitioner is entitled to compensation.

I. Procedural History

Petitioner filed her petition on June 11, 2018. Pet. The next day, Petitioner sent medical records via compact disc to be filed. Pet'r's Exs. 1–6. Petitioner filed additional medical records on April 11, 2019, and May 9, 2019. Pet'r's Exs. 7–9, ECF Nos. 17, 20. Respondent filed his Rule 4(c) report, arguing against compensation, on July 25, 2019. Resp't's Rept., ECF No. 25. Petitioner filed additional medical records and a Vaccine Adverse Even Reporting System ("VAERS") report on September 5, 2019, and January 13, 2020. Pet'r's Exs. 10–12, ECF Nos. 27, 31.

On January 28, 2020, Petitioner filed an expert report from Lawrence Steinman, M.D. Pet'r's Ex. 13, ECF No. 34. On June 6, 2020, Respondent filed a responsive expert report from Christopher Gibbons, M.D., M.M.Sc. Resp't's Ex. A, ECF No. 38. Petitioner filed a supplemental expert report from Dr. Steinman on October 28, 2020. Pet'r's Ex. 30, ECF No. 41. Respondent filed a supplemental expert report from Dr. Gibbons on February 18, 2021. Resp't's Ex. C, ECF No. 43.

Petitioner submitted a demand to Respondent on February 24, 2021, but Respondent filed a status report on April 5, 2021, indicating he reviewed the demand and was not interested in settlement at that time. ECF No. 45. Accordingly, on June 18, 2021, Petitioner filed an additional expert report from Dr. Steinman, and on July 30, 2021, Respondent filed an additional expert report from Dr. Gibbons. Pet'r's Ex. 33, ECF No. 47; Resp't's Ex. D, ECF No. 48. Petitioner filed an additional expert report from Dr. Steinman on September 2, 2021. Pet'r's Ex. 35, ECF No. 49.

On June 23, 2022, I held a Rule 5 conference in part to discuss Petitioner's filed evidence in support of her burden under *Althen* prong three. Min. Entry, docketed June 23, 2022. Petitioner stated that she would file a supplemental expert report addressing prong three. ECF No. 51. On June 24, 2022, Petitioner submitted a second demand to Respondent, but Respondent again was not interested in settlement. ECF Nos. 50, 52. On November 17, 2022, Petitioner submitted a supplemental expert report from Dr. Steinman. Pet'r's Ex. 36, ECF No. 55. On March 13, 2023, Respondent filed a responsive expert report from Dr. Gibbons. Resp't's ex. E, ECF No. 58.

On October 25, 2023, Petitioner filed a motion for a ruling on the record. Pet'r's Mot., ECF No. 60. On January 26, 2024, Respondent filed a response to Petitioner's motion requesting a decision be issued dismissing Petitioner's claim. Resp't's Response, ECF No. 64. Respondent noted that his expert disputed both diagnosis and causation. *Id.* at 3. Petitioner filed a reply on February 16, 2024. Pet'r's Reply, ECF No. 66. This matter is now ripe for adjudication.

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certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered.").

II. Factual History

a. Medical Records

1. Pre-Vaccination Medical Records

Petitioner's medical history is significant for anxiety, chest pain, back pain, and headaches. *See* Pet'r's Ex. 1. Petitioner has been followed by neurologists at Mecklenburg Neurological Associates ("MNA") since 2004 for headaches, neck pain, tinnitus, and paresthesias. *See e.g.*, Pet'r's Ex. 7 at 213, ECF No. 17; Pet'r's Ex. 12, ECF No. 31-1. Magnetic resonance imaging ("MRI") of her brain in 2004, 2009, and 2012 were normal. Pet'r's Ex. 7 at 213. MRIs of her cervical spine in 2009 and 2012 showed degenerative joint disease. *Id.* A 2009 electromyogram ("EMG") was normal. *Id.* A lumbar puncture reportedly done prior to 2012 had borderline cerebral spinal fluid pressure. *Id.* She suffered a "low pressure headache afterwards and required a blood patch." *Id.*

On October 27, 2009, Petitioner presented to MNA for tingling in her left foot that spread to her entire left leg and left arm. Pet'r's Ex. 12 at 131. History notes indicated Petitioner had received a flu shot in her left deltoid "just before the tingling started."[4] *Id.* The impression of Dr. Thor Erik Borresen was "[p]aresthesias with objective normal examination." *Id.* at 133. Dr. Borresen noted Petitioner's condition "could be a minor reaction to the flu shot" and that her symptoms should improve in one to two weeks. *Id.*

On November 16, 2012, Petitioner presented to Dr. Borresen for evaluation of paresthesias in her hands and feet. Pet'r's Ex. 12 at 8. Petitioner reported that she received a flu shot on September 12, 2012, and one week later, on September 19, 2012, developed numbness and tingling in her feet, lower legs, and hands. *Id.* She reported a similar reaction to her flu shot two years ago but that last year she did not have any side effects.[5] *Id.* Dr. Borresen "reassured and advised [Petitioner] to avoid the flu shots since she has had side effects of paresthesias." *Id.* at 10.

Approximately 13 months prior to the vaccination at issue, on September 15, 2014, Petitioner was seen at Randolph Internal Medicine (her primary care office) for bacterial sinusitis, right leg pain, and "[j]erky body movements." Pet'r's Ex. 1 at 469. During this visit she described "a reoccurrence of random body twitches," that occurred about once per day. *Id.* She reported that she had seen MNA neurologist Dr. Borresen in the past and had a normal electroencephalogram ("EEG") two months ago. *Id.*

Two months prior to the vaccination at issue, on August 19, 2015, Petitioner saw Dr. Gregory Collins at her primary care office for "a sensation of her throat being swollen and on the verge of closing down." Pet'r's Ex. 1 at 731. She received a Kenalog injection in the emergency department ("ED") that she reported provided some relief. *Id.* At that time, Petitioner was noted to be under a great deal of stress, due to the death of her parents and losing her job. *Id.* Her ongoing

[4] Medical records indicate Petitioner received a flu vaccine on November 2, 2009, which would be after this visit. *See* Pet'r's Ex. 1 at 12.

[5] Two years prior to this visit would be 2010. There are no medical records indicating a reaction to a flu vaccine in 2010. *See* Pet'r's Ex. 1 at 12.

problem list included anemia, anxiety, asthma, costochondritis (inflammation of the cartilage in the rib cage), gastroesophageal reflux disease ("GERD"), goiter, irritable bowel syndrome ("IBS"), scalp psoriasis, a thyroid nodule, and vitamin D deficiency. *Id.* Her active medications were Advair, Allegra, Singulair, prednisone, rabeprazole, Xanax, Zoloft, and vitamin D3, as well as diabetic supplies, including test strips and lancets. *Id.* at 731–32. Dr. Collins believed her symptoms were related to GERD. *Id.* at 733.

2. Vaccination

On October 5, 2015, Petitioner presented to her primary care office and was seen by Ashley Britt Phillips, P.A. Pet'r's Ex. 1 at 744. She complained of chest pain, left arm pain, and numbness. *Id.* She reported the pain was "in the left side of her lower jaw and radiate[d] into her left chest [] and down the arm. She [] had some mild numbness in the left arm." *Id.* Petitioner also had some tightness on the left side of her neck. *Id.* Examination revealed "significant tenderness and spasm in the left trapezius muscle and her left costochondral joints." *Id.* at 745. Her electrocardiogram ("ECG") was normal. *Id.* at 746. She was diagnosed with acute chest wall pain and a muscle spasm in her neck, for which she was prescribed a muscle relaxer and Medrol Dosepak. *Id.* It was also noted that Petitioner had a lot of anxiety and was going to increase her Zoloft dosage as recommended by her psychiatrist. *Id.* Petitioner received the subject flu vaccination at 39 years old. *Id.* at 749.

3. Post-Vaccination Medical Records

Ten days later, on October 15, 2015, Petitioner presented to the ED at Novant Health Presbyterian Medical Care with complaints of feeling "off balance" and "'waves' of generalized numbness," as well as head pressure and sensations that were "almost like spasms," with the left side greater than the right. Pet'r's Ex. 2 at 7. She also reported numbness and tingling "all over 'from the neck' down intermittently." *Id.* Neurological examination, lab work, and a computed tomography ("CT") scan were normal. *Id.* at 9–14. The diagnoses were paresthesias and urinary tract infection. *Id.* at 10, 14.

Four days later, on October 19, 2015, Petitioner returned to the ED reporting that her "major muscle groups hurt and [were] fatigued," and she felt a "sharp stabbing pain in her head." Pet'r's Ex. at 36. Petitioner reported "a professed history of undifferentiated connective tissue disease." *Id.* at 37. She also reported that she had a flu shot two weeks prior and "later that night after receiving the vaccine, she felt chills, generalized upper respiratory congestion[,] and generally fatigued." *Id.* She denied any fevers. *Id.* Her congestion continued but overall, she initially felt better. *Id.* "[Six] days ago[,] she began to experience waves of bilateral head to toe numbness and paresthesias which would wax and wane and spontaneously resolved." *Id.* "Over the last several days [Petitioner] [] had continued episodes of numbness" and reported "proximal muscle twitching which was bilateral with intermittent random fasciculations and generalized proximal muscle fatigue. This ha[d] been intermittent, waxing and waning over the weekend until this morning where she was walking at Lowe's and seemed to have more difficulty." *Id.* Petitioner also reported she had a similar presentation with her paresthesias from a flu shot five years ago.[6]

[6] Five years prior to this appointment was 2010. However, medical records only indicate a flu shot from that time in 2009 and 2012. *See* Pet'r's Ex. 1 at 12.

Id. She "[w]as given some type of prescription for this by her primary doctor[7] that she [could not] remember exactly what it was but ultimately her symptoms resolved[,] and she has had no further issues from that until her recent flu shot [two] weeks ago." *Id.* "Reaction to [flu] immunization" was listed in diagnoses. *Id.* at 42. Dr. Josie B. Bowen wrote:

> Patient with strange constellation of symptoms with a nonfocal neurologic exam[ination] here. The only objective criteria and date I can find is that her white blood cell count is now up to 16.5 with no fever and no other complaints of other infectious process. Remainder of her workup is unremarkable. She has showed me a copy of the report of a negative MRI with and without contrast of her brain done in 2013. This is certainly reassuring. She does not look ill. She in fact has felt a little bit better throughout her observation process here. I discussed her case with Jeffrey Schmidt with neurology. He does not think any other further treatment, further imaging, testing or admission to the hospital is warranted and that she can follow-up with her neurology [physician] tomorrow for her outpatient EEG and reassessment. . . . I am reassured that she does not have an emergency medical condition at this time.

Id.

The next day, on October 20, 2015, Petitioner described her symptoms to Dr. Borresen. Pet'r's Ex. 7 at 139. She felt "strongly that her symptoms [were] . . . sequala of a recent flu vaccine" two weeks ago. *Id.* Dr. Borresen ordered an EMG/nerve conduction study ("NCS"), an EEG, and a brain MRI, all of which were normal. *Id.* at 143, 120–24.

On October 29, 2025, Petitioner saw P.A. Phillips for chest cold symptoms for three weeks. Pet'r's Ex. 1 at 760. It was noted that Petitioner had two ED visits since she was last seen three weeks ago. *Id.* Petitioner "started getting waves of numbness and tingling in arms, legs and face and muscle weakness." *Id.* P.A. Phillips wrote that Petitioner "did have her flu shot when she was at our office on [October 5, 2015]. She [did] remember having this in 2010 and 2012 after her flu shot but it was milder." *Id.*

Petitioner returned to MNA on November 3, 2015. Pet'r's Ex. 7 at 132. The chief complaint was muscle twitches. *Id.* at 133. Petitioner was "convinced she ha[d] a mild case of [Guillain-Barré syndrome ("GBS")][8] following the flu vaccine." *Id.* at 132. Since her last visit, Petitioner started prednisone "[o]n her own" and felt it made a mild improvement in her symptoms overall. *Id.* Petitioner saw Dr. Borresen again on November 19, 2015. *Id.* at 125. History indicated she has had

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[7] The medical records do not indicate a prescription was given based on a reaction to a 2010 flu vaccine. *See supra* note 6.

[8] GBS is a "rapidly progressive ascending motor neuron paralysis of unknown etiology, frequently seen after an enteric or respiratory infection." *Guillain-Barré Syndrome*, DORLAND'S MED. DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=110689 (last visited June 17, 2025). "It begins with paresthesias of the feet, followed by flaccid paralysis of the entire lower limbs, ascending to the trunk, upper limbs, and face; other characteristics include slight fever, bulbar palsy, absent or lessened tendon reflexes, and increased protein in the cerebrospinal fluid without a corresponding increase in cells." *Id.*

a reaction three times after flu vaccinations. *Id.* Following the October 2015 flu vaccination, "she felt malaise, fevers, and then increasing paresthesias and muscle twitches and feeling weakness." *Id.* It was noted that in January, she was in a motor vehicle accident. *Id.* At the time, she did not have any back pain. *Id.* But in March, she complained of localized back pain near her bra line that was described as sharp. *Id.* After discussing her current symptoms, Dr. Borresen wrote, Petitioner "may have some minor reaction to the flu shot but she does not have evidence for [GBS]. She has a tendency to somatization and worry which is most likely going on. We decided to [] check laboratory tests for muscle diseases, autoimmune disease, and referred for physical therapy." *Id.*

On November 30, 2015, Petitioner presented for physical therapy. She reported that she began experiencing muscle spasms, weakness, and tingling in her bilateral upper and lower extremities about one week after her flu vaccination. Pet'r's Ex. 4 at 2. A workup on December 29, 2015, ruled out multiple sclerosis ("MS")[9] and amyotrophic lateral sclerosis ("ALS").[10] Pet'r's Ex. 7 at 113.

On January 4, 2016, Petitioner saw Dr. T. Rao at The Neurological Institute in Charlotte, North Carolina for further evaluation. Pet'r's Ex. 6 at 26. She explained that she received a flu shot on October 5, 2015, then around October 13, 2015, she developed numbness and tingling of the arms and legs as well as muscle spasms and weakness. *Id.* She self-treated with prednisone that she had at home for her asthma. *Id.* Petitioner reported to Dr. Rao that she had seen a neurologist who believed her symptoms could be a reaction to the flu shot. *Id.* Dr. Rao's differential diagnoses were transverse myelitis ("TM"),[11] GBS, or chronic inflammatory demyelinating polyneuropathy ("CIDP").[12] *Id.* at 28.

Petitioner was still having headaches, waves of tingling, and twitches when she returned to Dr. Borresen on January 6, 2016. Pet'r's Ex. 7 at 103. He noted that they had "not found an underlying etiology" for her symptoms and encouraged her "to focus on rehabilitation and symptomatic treatment." *Id.* On September 9, 2016, Petitioner returned to MNA with muscle twitching, cramping, and spasms, all of which were noted to have begun after a flu shot in 2015. Pet'r's Ex. 3 at 119. She explained that the spasms and cramping were mainly in her thighs but that she was experiencing intermittent twitching throughout her body. *Id.* Petitioner noted that a stabbing pain accompanied her muscle twitches; she further stated that these symptoms fluctuated, sometimes lasting for hours. *Id.* Petitioner continued to see the neurologists at MNA in 2017 for similar symptoms with no abnormal results or additional diagnoses. *See* Pet'r's Ex. 7 at 4–75.

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[9] MS is "a disease in which there are foci of demyelination throughout the white matter of the central nervous system, sometimes extending into the gray matter; symptoms usually include weakness, incoordination, paresthesias, speech disturbances, and visual complaints." *Multiple Sclerosis*, DORLAND'S MED. DICTIONARY ONLINE.

[10] ALS is "a motor neuron disease marked by progressive degeneration of the neurons that give rise to the corticospinal tract and of the motor cells of the brainstem and spinal cord, resulting in a deficit of upper and lower motor neurons." *Amyotrophic Lateral Sclerosis*, DORLAND'S MED. DICTIONARY ONLINE.

[11] TM is a "myelitis in which the functional effect of the lesions spans the width of the entire cord at a given level." *Transverse Myelitis*, DORLAND'S MED. DICTIONARY ONLINE.

[12] CIDP is "a slowly progressive, autoimmune type of demyelinating polyneuropathy characterized by progressive weakness and impaired sensory function in the limbs and enlargement of the peripheral nerves, usually with elevated protein in the cerebrospinal fluid." *Chronic Inflammatory Demyelinating Polyneuropathy*, DORLAND'S MED. DICTIONARY ONLINE.

On April 26, 2017, Petitioner presented to neurologist Dr. Justin Mhoon at Duke Health Neurology. Pet'r's Ex. 5 at 12. Dr. Mhoon wrote that Petitioner had dysesthesias[13] and dysautonomia[14] following a flu vaccine in 2015. *Id.* Neurologic examination revealed "reduced temperature and pinprick sensation in the feet bilaterally," and she also had "significant autonomic symptoms." *Id.* His assessment was that Petitioner "may have [SFN]. She does have prediabetes[, but] may be related to postvaccination small fiber neuritis." *Id.* He ordered a skin biopsy for the suspected SFN. *Id.* The skin biopsy result showed "significantly reduced [e]pidermal [n]erve [f]iber [d]ensity, consistent with [SFN]." *Id.* at 15. Dr. Mhoon noted the SFN may be related to her vaccination or pre-diabetes. *Id.* at 53. A full serologic workup was unremarkable. *Id.* at 67.

Petitioner saw Dr. Kurt Washburn at MNA October 5, 2017, with fluctuating and intermittent symptoms including headaches, twitching spells, and muscle spasms. Pet'r's Ex. 7 at 9. History noted a recent diagnosis of SFN from Dr. Mhoon. *Id.* at 9. History also noted that Petitioner was hospitalized in August 2017 for "myoclonus/trouble walking/weakness." *Id.* (internal quotations omitted). Having reviewed the extensive workups ordered by Dr. Rao, Dr. Mhoon, and the hospital, the results of which were all normal, except for the skin biopsy, Dr. Washburn believed that the etiology of Petitioner's symptoms remained unclear. *Id.* at 9, 13. He noted that a diagnosis of SFN "may explain random/twitches/cramps/pains," but that the "extensive inpatient workup in August 2017 with repeat imaging/labs/testing etc. [] was again unremarkable." *Id.* at 13. He further noted that Petitioner was being treated for depression and anxiety, and he had "suspicions that [Petitioner] may have a somatoform[15] disorder given her numerous unexplained symptoms." *Id.* He advised Petitioner to "follow up with [her psychiatrist] to discuss [the] possible impact of her mental health on her unexplained physical symptoms." *Id.*

Petitioner continued to see Drs. Borrresen, Washburn, Rao, and Mhoon through 2017 with no significant updates in her condition. *See* Pet'r's Exs. 5–7.

No other relevant medical records were filed.

III. Expert Reports

A. Expert Qualifications

1. Petitioner's Expert, Lawrence Steinman, M.D.

Dr. Steinman is a board-certified neurologist who has practiced adult and pediatric neurology for 40 years. Pet'r's. Ex. 13 at 2, ECF No. 34-1. He received his medical degree from Harvard University and subsequently completed an internship and residencies at Stanford University Hospital. Pet'r's Ex. 34 at 2, ECF No. 47-2. He is currently a Professor at Stanford

[13] Dysesthesia is the "distortion of any sense, especially of that of touch" or "an unpleasant abnormal sensation produced by normal stimuli." *Dysesthesia*, DORLAND'S MED. DICTIONARY ONLINE.
[14] Dysautonomia is the "malfunction of the autonomic nervous system." *Dysautonomia*, DORLAND'S MED. DICTIONARY ONLINE.
[15] Somatoform denotes "physical symptoms that cannot be attributed to organic disease and appear to be of psychic origin." *Somatoform*, DORLAND'S MED. DICTIONARY ONLINE.

University in the Departments of Neurology and Neurological Science, and Pediatrics and Genetics. *Id.* He has "cared for hundreds of adults and children with various forms of neuroinflammatory diseases" including SFN, GBS, CIDP, TM, and MS. Pet'r's Ex. 13 at 2. Dr. Steinman has conducted research on and published numerous publications on neurology and the immune system. *See id.* at 4; Pet'r's Ex. 34 at 6–50

2. Respondent's Expert, Christopher Gibbons, M.D., M.M.Sc.

Dr. Gibbons is a board-certified neurologist. Resp't's Ex. A at 1, ECF No. 38-1. He received his medical degree from Albert Einstein College of Medicine and his master's in medical science from Harvard-MIT Health Science and Technology. Resp't's Ex. B at 1, ECF No. 38-2. He completed an internship at Greenwich-Yale New Haven Hospital and a residency at Johns Hopkins Hospital. *Id.* He is currently an Attending Physician of Neurology at Beth Israel Deaconess Medical Center, an Attending Physician at the Joslin Diabetes Center, and an Associate Professor of Neurology at Harvard Medical School. *Id.* Dr. Gibbons has "treated thousands of patients with [SFN] and reviewed tens of thousands of skin biopsy slides for evaluation of [SFN] over the past [two] decades." Resp't's Ex. A at 1. Dr. Gibbons has published several articles on SFN. *Id.*; Respt's Ex. B at 23–30.

B. Expert Opinions

1. Petitioner's Expert, Dr. Steinman

Dr. Steinman opined, "more likely than not," that the 2015 flu vaccine Petitioner received triggered her SFN. Pet'r's Ex. 13 at 22. He proposed a theory based on molecular mimicry "showing that there are similarities in amino acid sequence between [a component in the vaccine and] α3 [acetylcholine receptor ("AChR")],[16] which is attacked by the immune system in [SFN]." *Id.* He opined a proximate temporal relationship between the vaccine and injury is fulfilled because an onset of six days is consistent with epidemiologic studies of inflammatory neuropathy after the swine flu vaccine. *Id.* at 23.

a. Diagnosis

Dr. Steinman began by describing SFN. Pet'r's Ex. 13 at 7. SFN is a disorder affecting the small sensory cutaneous nerves. Pet'r's Ex. 17 at 2, ECF No. 34-5.[17] It occurs when "damage to the peripheral nerves predominantly or entirely affects the small myelinated (Aδ) fibers or unmyelinated C fibers." Pet'r's Ex. 31 at 3, ECF No. 41-2.[18] "[A]ntibodies to α3-AChR are associated with autoimmune autonomic ganglionopathy in [SFN]." Pet'r's Ex. 13 at 7 (citing Pet'r's Ex. 18 at 1, 4, ECF No. 34-6 (stating that the nicotinic ganglionic acetylcholine receptor

[16] The α3 AChR is also referred to as the nicotinic or ganglionic acetylcholine receptor throughout this Ruling.

[17] *Small Fiber Neuropathy*, JOHNS HOPKINS MEDICINE, https://www.hopkinsmedicine.org/neurology_neurosurgery/centers_clinics/peripheral_nerve/conditions/small_fiber_sensory_neuropathy.html (Jan. 27, 2020).

[18] Alexandra Hovaguimian & Christoper H. Gibbons, *Diagnosis and Treatment of Pain in Small Fiber Neuropathy*, 15 CURRENT PAIN HEADACHE REPS. 193 (2012). This is also cited by Respondent.

(α3-AChR) antibody causes autoimmune dysautonomia and finding that patients with SFN had medium levels of the antibodies)).[19] Most patients have length-dependent SFN, in which they "experience sensory disturbances that start in the feet and progress upwards." *Id.* (quoting Pet'r's Ex. 17 at 2). Length-dependent SFN is often due to diabetes or impaired glucose metabolism (pre-diabetic state); but in a significant number of patients, no underlying etiology is found and thus they have idiopathic SFN. *Id.* Some patients have non-length-dependent SFN, in which they "experience sub-acute onset sensory disturbances diffusely over the whole body." *Id.* (quoting Pet'r's Ex. 17 at 2). Non-length-dependent SFN is almost always idiopathic. *Id.*

"Symptoms of SFN can vary widely in severity." Pet'r's Ex. 31 at 4. Symptoms are usually sensory in nature and can include a pins and needles sensation, cold-like pain, tingling, numbness, burning sensation, and electric shock-like pain. *Id.*; Pet'r's Ex. 17 at 2. Because the large sensory fibers are not involved in SFN, patients do not have balance problems or muscle weakness. Pet'r's Ex. 17 at 2. Diagnosis of SFN is based on history, clinical examination, and laboratory findings such as EMG/NCS (to rule out involvement of motor and large sensory nerve fibers) and skin biopsies (to confirm loss of cutaneous nerve innervation). *Id.* "One of the hallmarks of a pure [SFN] is a normal or near normal physical and neurologic examination." Pet'r's Ex. 31 at 4. There may be decreased pinprick, decreased thermal sensation, or hyperalgesia in the affected region, as well as mildly decreased vibratory sensation. *Id.*

Dr. Steinman agreed with Petitioner's treating physician that SFN is the correct diagnosis. *See* Pet'r's Ex. 33 at 3, ECF No. 47-1. He relied primarily on the diagnosis made by one of Petitioner's treating neurologist, Dr. Mhoon, which was confirmed by skin biopsy. Pet'r's Ex. 30 at 4, ECF No. 41-1 (citing Pet'r's Ex. 5 at 15). While Respondent's expert, Dr. Gibbons, opined the skin biopsy result from Therapath was likely a false positive, Dr. Steinman noted that Therapath results are interpreted and attested by board-certified pathologists and neurologists and deferred to them on this point. *Id.*; Pet'r's Ex. 33 at 3.

b. Causation

The mechanistic theory proposed by Dr. Steinman for how the flu vaccine can cause SFN was molecular mimicry. Pet'r's Ex. 13 at 8. He explained how shared structures in a virus, bacteria, or a vaccine can trigger a cross-reactive response to self and initiate autoimmune disease. *Id.* at 8–9 (citing Pet'r's Ex. 20).[20] In his 1993 article, Dr. Steinman wrote that molecular mimicry is an "evolutionary adaptation whereby viruses and bacteria attempt to fool the body into granting them free access. Such mimicry works by showing the immune system stretches of amino acids that look like self." Pet'r's Ex. 20 at 5. A response "can begin even if the molecular mimicry is not quite exact."[21] *Id.* While cross-reactive immune responses between viruses and hosts can be

[19] Andrew McKeon et al., *Ganglionic Acetylcholine Receptor Autoantibody*, 66 ARCHIVES NEUROLOGY 735 (2009).

[20] Lawrence Steinman, *Autoimmune Disease*, 269 SCI. AM. 106 (1993).

[21] For example, studies have induced disease in mice "by exposing them to a short stretch of 10 amino acids, of which only five were actually identical to myelin basic protein." Pet'r's Ex. 20 at 5. Another study "demonstrated that hepatitis B virus polymerase shared a stretch of just six amino acids with a part of the myelin basic protein molecule that causes [encephalomyelitis ("EAE")] in rabbits. When they immunized rabbits with this part of the virus, the animals developed inflammation in their brains." *Id.* Dr.

common, for an autoimmune disease to occur, the cross-reaction must take place at a "disease-related" epitope. Pet'r's Ex. 13 at 10 (quoting Pet'r's Ex. 24 at 3).[22]

After indicating that α3 AChR is a neural receptor that the immune system targets in SFN, Dr. Steinman used a three-step process to identify sequences that could implicate molecular mimicry between the flu vaccine and α3 AChR, the "disease related" epitope. Pet'r's Ex. 13 at 8, 19. First, Dr. Steinman conducted a BLAST[23] search to determine whether there was any similarity, or sequence homology, between the components of the 2015-2016 flu vaccine[24] and the α3 AChR that is targeted in SFN. *Id.* at 13.[25] He started by looking at one of the proteins in the H1N1 A/California component, nucleocapsid. *Id.* He found the "sequence RESRNPGNAE has [five] of 10 identical amino acids." *Id.* at 14. He also found another component of the vaccine had sequence homology with the α3 nicotinic AChR.[26] *Id.* at 17–18. This BLAST search was directed to the hemagglutinin (A/California/07/2009(H1N1)) found in the 2015 vaccine. *Id.* at 18. He found the sequence DKAKIDLVLIG has a stretch with "[seven] of 11 amino acid identity between a component of the 2015 [flu] vaccine and α3 nicotinic AChR." *Id.* He opined that such degrees of identity have "been shown to be sufficient to trigger clinical[ly] relevant neuroinflammation in animal models." *Id.*

To prove such, Dr. Steinman next filtered the areas of alignment between the vaccine and the α3 AChR from the BLAST search and "eliminate[d] sequence homologies that [were] below a threshold that ha[d] been shown to induce neuroinflammation with clinical symptoms like paralysis in the [experimental encephalomyelitis ("EAE")] model." Pet'r's Ex. 13 at 18. Relying on medical literature, Dr. Steinman explained how the sequences he found were significant due to the presence of five identical amino acids in a longer sequence. *See id.* For support, he cited studies by Gautam et al. which found "[five] of 12 amino acids, not even consecutive amino acids, was

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Steinman concluded the research "suggests that molecular mimicry between viruses or bacteria and self may be critical in initiating autoimmune responses." *Id.*

[22] Robert S. Fujinami et al., *Molecular Mimicry, Bystander Activation, or Viral Persistence: Infections and Autoimmune Disease*, 19 CLINICAL MICROBIOLOGY REVS. 80 (2006).

[23] A BLAST (Basic Local Alignment Search Tool) search "finds regions of similarity between biological sequences. The program compares nucleotide or protein sequences to sequence databases and calculates the statistical significance." *Basic Local Alignment Search Tool*, NATIONAL INSTITUTES OF HEALTH (last visited May 23, 2025), https://blast.ncbi.nlm.nih.gov/Blast.cgi.

[24] The components of the 2015-2016 flu vaccine according to a release from the FDA are: A/California/7/2009 (H1N1)-like virus, A/Switzerland/9715293/2013 (H3N2)-like virus, a B/Phuket/3073/2013-like virus, a B/Brisbane/60/2008-like virus. Pet'r's Ex. 13 at 8 (citing Pet'r's Ex. 19). Dr. Steinman noted that it is unclear from the record whether Petitioner received a trivalent or quadrivalent vaccine, and that the B/Brisbane component is only in the quadrivalent vaccine. *Id.*

[25] For a complete explanation of Dr. Steinman's investigation, including his discussion on the number of amino acids required for homology relevant to molecular mimicry as well as the procedure he followed in conducting his BLAST searches, see Pet'r's. Ex. 13 at 8–22.

[26] Dr. Steinman also conducted a BLAST search for the hemagglutinin in B/Brisbane/60/2008 in the quadrivalent flu vaccine (which he admitted Petitioner may have not received) and tested the other flu B component, Phuket/3073/2013 (B/Malaysia/3120318925/2013). Pet'r's Ex. 13 at 14–17. He found two "notable sequences" from these BLAST searches. *Id.* at 17.

sufficient to trigger [EAE]." *Id.* at 11 (citing Pet'r's Ex. 26, ECF No. 34-14;[27] Pet'r's Ex. 27, ECF No. 34-15;[28] Pet'r's Ex. 28, ECF No. 34-16).[29] Therefore, Dr. Steinman determined the sequences identified have a degree of homology "sufficient to trigger clinical[ly] relevant neuroinflammation." *Id.* at 18.

The third step of his process "retains those peptide sequences identified in the first two steps, only if they have been identified by other investigators using one and/or two other US government databases." Pet'r's Ex. 13 at 18. Dr. Steinman searched the sequence, RESRNPGNAE, which had five of 10 identical amino acids between a component of the vaccine (the nucleocapsid protein of the H1N1 A/California component) and the α3 AChR in the Immune Epitope DataBase ("IEDB").[30] *Id.* at 12–13, 20–21. The sequence appeared in the IEDB, which Dr. Steinman asserted was evidence that it was an epitope that had been reported in humans. *Id.* at 18, 20. The epitope also appeared in the Influenza Research Database ("IRD").[31] *Id.* at 18, 21. Dr. Steinman opined that because it was reported in the IEDB and IRD, an immune attack to this epitope could cause SFN. *Id.* at 20, 22. The sequence DKAKIDLVLIG, which had seven of 11 amino acid identity between the hemagglutinin component and α3 AChR, was found in the IEDB, but not in the IRD as of January 19, 2020. *Id.* at 21. He summarized that the findings of his three-step process "make a compelling theory that molecular mimics in the 2015-2016 [flu] vaccine received by [P]etitioner could trigger immunity to α3 AChR culminating in [SFN]. This was due to homologies with antigen that are homologous mimics of the vaccine and that are targeted in [SFN] based on [the studies cited]." *Id.* at 22.

In his final expert report, where he focused on *Althen* prong three, Dr. Steinman added a layer to his theory based on a recall response. Pet'r's Ex. 36 at 2, ECF No. 55-1 (explaining that the diagnosis of SFN was made after the 2015 flu vaccine and not earlier because "after several challenges a recall response ensued"). He noted Petitioner received a flu vaccine containing the same hemagglutinin component as the vaccine at issue in 2011, 2012, 2013, and 2014. *Id.* at 3. Dr. Steinman cited "sound and reliable literature for showing how repeated immunization with a molecular mimic could finally result in a pathologic response to the molecular mimic." *Id.* at 5

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[27] Anand M. Gautam et al., *A Polyalanine Peptide with Only Five Native Myelin Basic Protein Residues Induces Autoimmune Encephalomyelitis*, 176 J. EXPERIMENTAL MED. 605 (1992). Dr. Steinman is a named author in this paper.

[28] Anand M. Gautam et al., *Minimum Structural Requirements for Peptide Presentation by Major Histocompatibility Complex Class II Molecules: Implications in Induction of Autoimmunity*, 91 IMMUNOLOGY 767 (1994). Dr. Steinman is a named author in this paper.

[29] Anand M. Gautam et al., *A Viral Peptide with Limited Homology to a Self Peptide Can Induce Clinical Signs of Experimental Autoimmune Encephalomyelitis*, 161 J. IMMUNOLOGY 60 (1998). Dr. Steinman is a named author in this paper.

[30] The IEDB "catalogs experimental data on antibody and T cell epitopes studied in humans, non-human primates, and other animal species in the context of infectious disease, allergy, autoimmunity and transplantation. The IEDB also hosts tools to assist in the prediction and analysis of epitopes." IMMUNE EPITOPE DATABASE, (last updated May 23, 2025), https://www.iedb.org/. The IEDB is a freely available resource funded by the National Institute of Allergy and Infectious Diseases. Id.

[31] The IRD "is a US NIH/NIAID-funded, freely-available online bioinformatics resource for influenza virus data search, analysis and visualization." Richard H. Scheuermann, *Influenza Research Database (IRD)*, J. CRAIG VENTER INSTITUTE (last visited May 23, 2025), https://www.jcvi.org/research/influenza-research-database-ird.

(citing Pet'r's Ex. 43, ECF No. 56-7;[32] Pet'r's Ex. 44, ECF No. 56-8).[33] Kappos et al. was a double-bind trial comparing "an altered peptide ligand of myelin basic protein with placebo, evaluating their safety and influence on [MRI] in relapsing-remitting [MS]." Pet'r's Ex. 43 at 1. Dr. Steinman explained that "when the altered myelin peptide was given . . . weekly via subcutaneous injection, there was evidence of reduced inflammatory lesion activity on MRI, a long sought-after result, and the primary endpoint in the study." Pet'r's Ex. 36 at 4 (citing Pet'r's Ex. 43). The trial was discontinued due to hypersensitivity in 9% of the patients. *Id.* He added that "the adverse reaction did not manifest in most patients until more than 10 injections." *Id.* Bielekova et al. was a similar trial where "three patients out of seven developed transient clinical worsening of their relapsing MS, with dramatic increases in inflammatory lesions on MRI." *Id.* at 4–5 (citing Pet'r's Ex. 44).

Thus, Dr. Steinman concluded "it can take multiple exposures to the same molecular mimic before there is a full blown clinical expression of its delirious effects." Pet'r's Ex. 36 at 5. He opined the recall response "supports onset of [SFN] in [P]etitioner six days after the 2015-2016 [flu] immunization." *Id.* "A recall response to the same area of mimicry between the [flu] vaccine and the acetylcholine receptor required multiple injections of the very same antigenic region contained in the hemagglutinin of [[flu] A virus (A/California/07/2009(H1N1))]. She received such injections in 2012, 2013, and 2014." *Id.*

To show that Petitioner's onset of SFN occurred about six days after the October 5, 2015 vaccine, Dr. Steinman relied on the medical records. Pet'r's Ex. 13 at 22; Pet'r's Ex. 30 at 2.

> She state[d] she underwent a flu shot [two] weeks ago, and later that night after receiving the vaccine[] she felt chills, generalized upper respiratory congestion[,] and generally fatigued. [Six] days ago[,] she began to experience waves of bilateral head to toe numbness and paresthesias which would wax and wane and spontaneously resolved. She denied focal weakness and state[d] she was walking normally. [Five] days ago[,] she went to see her [physician] with neurology and was scheduled for an outpatient EEG for tomorrow secondary to her [history] of leg jerks which preceded her other presenting events today. [Four] days ago[,] she was seen in the E[D] with worsening paresthesias and generalized malaise. She had extensive workup which was essentially unremarkable.

Pet'r's Ex. 30 at 2 (quoting Pet'r's Ex. 2 at 37). In response to Dr. Gibbons' opinion that onset was prior to vaccination because Petitioner had symptoms of numbness and tingling in 2005, 2009, 2012, and 2013, Dr. Steinman acknowledged those symptoms in years prior but ultimately concluded SFN was not the diagnosis until after the 2015 vaccination based on the medical records reproduced above. *Id.*

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[32] Ludwig Kappos et al., *Induction of a Non-Encephalitogenic Type 2 T Helper-Cell Autoimmune Response in Multiple Sclerosis After Administration of an Altered Peptide Ligand in a Placebo-Controlled, Randomized Phase II Trial*, 6 NATURE MED. 1176 (2000).

[33] Bibiana Bielekova et al., *Encephalitogenic Potential of the Myelin Basic Protein Peptide (Amino Acids 83-99) in Multiple Sclerosis: Results of a Phase II Clinical trial with an Altered Peptide Ligand*, 6 NATURE MED. 1167 (2000).

Relying on Schonberger et al.[34] "the best surrogate to use in this case," Dr. Steinman opined Petitioner's six-day onset of SFN "is consistent with an increase in inflammatory neuropathy in a classic epidemiology study looking at timing of onset of inflammatory neuropathy after the 1976 swine flu campaign." Pet'r's Ex. 30 at 5 (citing Pet'r's Ex. 29, ECF No. 34-17). Schonberger et al. reviewed case reports from the Centers for Disease Control and Prevention ("CDC") of GBS after the flu vaccine administration and found, on average, an onset between two and three weeks. Pet'r's Ex. 29 at 7–8. Based on this, Dr. Steinman opined "a proximate temporal relationship between vaccination and injury is fulfilled." *Id.* (internal quotations omitted).

2. Respondent's Expert, Dr. Gibbons

Dr. Gibbons disagreed that Petitioner has SFN and opined that even if she does have SFN, it was not caused by the flu vaccine, but rather by her pre-diabetes. *See* Resp't's Ex. A at 4, 6.

a. Diagnosis

First, Dr. Gibbons explained that "symptoms of neuropathy are generally subdivided into 'positive' and 'negative' phenomena. Positive symptoms are defined as the onset of a sensation (tingling, burning, stabbing etc[.]) that are noted by a patient." Resp't's Ex. C at 1, ECF No. 43-1. In contrast, "negative symptoms are due to degeneration of the nerve," "defined as a loss of sensation[,] and are typically reported as numbness (or absence of sensation)." *Id.*; Resp't's Ex. E at 2, ECF No. 58-1. "Negative symptoms occur with loss of axonal integrity and cell death. With cell death or axonal disruption, sensory transmission is no longer possible and symptoms of 'numbness' are permanent. Thus, symptoms of numbness due to neuropathy do not come in waves, and do not tend to fluctuate in severity." Resp't's Ex. C at 1; *see* Resp't's Ex. E at 2 ("Among the thousands of patients [Dr. Gibbons] has treated with neuropathy, [he] ha[s] not found 'bilateral waves head to toe numbness and paresthesia' to be a symptom of neuropathy."). He added that if "numbness is reported over the whole body, and it is secondary to a neuropathy, such a finding would be unequivocally identifiable on examination because there would be permanent and profound small nerve fiber damage throughout the body." Resp't's Ex. C at 1.

Dr. Gibbons opined that Petitioner's symptoms are not consistent with a diagnosis of SFN. Resp't's Ex. A at 3. He opined muscle twitching, myoclonus, and ataxia are not symptoms of SFN. *Id.* He stated Petitioner had "waves of numbness throughout her body" that would come and go and opined that numbness from SFN does not occur in waves. *Id.* He also noted Petitioner had "multiple instances of severe weakness and inability to walk . . . which cannot be explained in any way by a diagnosis of [SFN]." *Id.* at 4. Finally, he noted Petitioner's neurological sensory examinations were "almost entirely normal." *Id.* Thus, Dr. Gibbons opined a diagnosis of SFN "is in doubt because [] the diverse symptoms and repeatedly normal examination findings [] do not support the diagnosis." *Id.*

Dr. Gibbons did acknowledge that on examination of Petitioner, Dr. Mhoon noted reduced pinprick sensation to midfoot that could be consistent with SFN. Resp't's Ex. A at 4 (citing Pet'r's

[34] Lawrence B. Schonberger et al., *Guillain Barré Syndrome Following Vaccination in the National Influenza Immunization Program, United States, 1976-1977*, 110 AM J. EPIDEMIOLOGY 105 (1979).

Ex. 5 at 5). However, Dr. Gibbons wrote "these abnormalities were only noted in the distal feet, not throughout the rest of the body where the symptoms were occurring." *Id.* Additionally, he highlighted that Dr. Mhoon noted that SFN would not explain all of Petitioner's symptoms. *Id.*

As to the skin biopsy result, Dr. Gibbons observed it was only abnormal at one of the two biopsy sites, and only "mildly abnormal." *Id.* Resp't's Ex. A at 5 ("The value at the left thigh was 7.33 fibers/mm with normal >8.3 fibers/mm. The value at the left calf was 8.49 fibers/mm, which is normal."); *see also* Resp't's Ex. D at 1, ECF No. 48-1 ("The only noted abnormality in this test is a slightly reduced nerve density at the distal thigh biopsy site."). Dr. Gibbons doubted the accuracy of this biopsy result from Therapath because he opined "results from Therapath are among the least reliable in the industry." Resp't's Ex. A at 5. According to Dr. Gibbons, repeat tests must be done often because the abnormal biopsy results do not match the clinical findings and when repeated, the biopsy results are usually normal. *Id.*; *see* Resp't's Ex. C at 2 (noting that "approximately 50% of patients with a reported [SFN] by biopsy were not reproduced on repeat testing"). Thus, he believed Petitioner's skin biopsy result was a "false positive" because Petitioner's symptoms and signs on examination did not match the pathologic findings. Resp't's Ex. C at 2 ("The slightly abnormal skin biopsy finding is not a particularly compelling case for [SFN] and does not fit with the clinical picture at all."); *see also* Resp't's Ex. A at 5 (opining the skin biopsy result does not fit with the clinical picture, which he opined as "severe diffuse involvement" because Petitioner reported twitches, numbness, and weakness over her entire body).

He proposed that even if Petitioner's biopsy result is accurate, "this is not a severe [SFN], it is a very mild neuropathy based on the numbers reported." Resp't's Ex. A at 5. Dr. Gibbons then acknowledged that it is "likely [Petitioner] has a mild small nerve fiber injury in her thigh" "given her several year history of pre-diabetes." *Id.*

b. Causation

Accordingly, Dr. Gibbons opined that even if Petitioner's abnormal biopsy result is correct and she has neuropathy, "the most plausible explanation . . . is pre-diabetes (which is the second most common cause of [SFN])," rather than "an alleged vaccine related injury which has never been reported in the literature." Resp't's Ex. D at 2; Resp't's Ex. C at 2; Resp't's Ex. A at 5–6.

Dr. Gibbons conducted a Pubmed search of the terms "neuropathy," "influenza," and "vaccination" to attempt to find a relationship. Resp't's Ex. A at 4. While 42 publications were identified, he did not find any reports of SFN associated with flu vaccination. *Id.* Based on this, he concluded "[t]here is no published evidence to suggest a link between [SFN] and the [flu] vaccination." *Id.*

Dr. Gibbons opined that Dr. Steinman's recall response theory "is based on a finding of a hypersensitivity reaction in response to administration of molecular mimic myelin basic protein in patients with [MS]." Resp't's Ex. E at 2. Dr. Gibbons opined that MS and SFN "are not related disorders, and any hypothesis drawn from one does not inform about the other. It is not clear how challenges with a purified mimic are in any way equivalent to a flu vaccination." *Id.*

In his final expert report, Dr. Gibbons opined the α3 neuronal acetylcholine receptor is not present in the class of nerve fibers alleged in this injury. Resp't's Ex. E at 2 (citing Resp't's Ex. E, Tab 1, ECF No. 57-1).[35] He stated it is "not seen in the unmyelinated nociceptive C fibers that are discussed in this alleged vaccine injury." *Id.* While he admitted that some diseases have been reported where there is an autoimmune response to the α3 AChR (such as myasthenia gravis and autoimmune autonomic ganglionopathy), those conditions are not suggested here. *Id.* (citing Resp't's Ex. E, Tab 2, ECF No. 57-2).[36]

Therefore, Dr. Gibbons opined that a recall response "has never been shown to be applicable in a flu vaccination, has only been studied in a purified mimic in a model of [MS,] and does not make biological sense because the wrong class of nerve fibers is implicated." Resp't's Ex. E at 3 (citing Resp't's Ex. E, Tab 1). He concluded, "there is no evidence of an association between a[] [flu] vaccine given in 2015 and the diagnosis of [SFN] in this case." Resp't's Ex. C at 2.

As to onset, Dr. Gibbons found "it difficult to ascertain a date of onset of symptoms suggestive of neuropathy given the frequency with which symptoms of numbness and tingling [were] reported from 2005-2013 prior to the onset of the alleged injury." Resp't's Ex. E at 1; *see also* Resp't's Ex. A at 6 (Dr. Gibbons noting Petitioner's symptoms of numbness, tingling, twitching, fatigue, and weakness began in 2005 and continued intermittently up to and after the date of vaccination in 2015.). Accordingly, he disagreed with Dr. Steinman "that there is a clear onset of symptoms [six] days post vaccination." *Id.* Dr. Gibbons noted Petitioner had symptoms of numbness and tingling noted in the medical records in 2005, 2009, 2012, and 2013 and thus opined, "the onset of symptoms was many years prior to the alleged vaccination." *Id.* (citing Pet'r's Ex. 7 at 174–79; Pet'r's Ex. 12 at 5–11, 81–117, 156, 218–20).

Dr. Gibbons stated the "most likely" cause of SFN, pre-diabetes, was not discussed as a potential cause of Petitioner's condition. Resp't's Ex. A at 4. He explained pre-diabetes refers to the above normal range of glucose levels that do not yet meet the criteria for diabetes. Resp't's Ex. D at 1. One of the risks associated with pre-diabetes is the development of small fiber and autonomic neuropathies. *Id.* He opined pre-diabetes is a "very common" cause of SFN. Resp't's Ex. A at 4 (citing references 3–5);[37] *see also* Resp't's Ex. D at 1 (citing Resp't's Ex. D, Tab 3);[38] Resp't's Ex. D, Tab 1.[39] He explained that Petitioner had a diagnosis of pre-diabetes in 2012 that was confirmed in follow-up visits in 2013 and 2014. Resp't's Ex. A at 4 (citing Pet'r's Ex. 1 at 156, 275; Pet'r's Ex. 12 at 53–65). Accordingly, Dr. Gibbons found it hard to believe "that the

[35] Anant Gharpure et al., *Agonist Selectivity and Ion Permeation in the a3b4 Ganglionic Nicotinic Receptor*, 104 NEURON 501 (2019).
[36] Steven Vernino et al., *Myasthenia Gravis with Autoimmune Autonomic Neuropathy*, 88 AUTONOMIC NEUROSCIENCE: BASIC CLINICAL 187 (2001).
[37] B.C. Callaghan et al., *Diabetes and Obesity are the Main Metabolic Drivers of Peripheral Neuropathy*, 5 ANNALS CLINICAL TRANSLATIONAL NEUROLOGY 397 (2018); J.R. Singleton et al., *Polyneuropathy with Impaired Glucose Tolerance: Implications for Diagnosis and Therapy*, 7 CURRENT TREATMENT OPTIONS NEUROLOGY 33 (2005); J.R. Singleton et al., *Microvascular Complications of Impaired Glucose Tolerance*, 52 DIABETES 2867 (2003). These articles were not filed.
[38] Lan Zhou, *Small Fiber Neuropathy*, 39 SEMINARS NEUROLOGY 570 (2019).
[39] Varo Kirthi et al., *Prevalence of Peripheral Neuropathy in Pre-Diabetes: a Systematic Review*,9 BMJ OPEN DIABETES RSCH. CARE e002040 (2021).

onset of symptoms reported in 2015 were now a new, and different disorder." Resp't's Ex. C at 1. He opined the "clear documentation of symptoms in the years prior to the alleged vaccine injury . . . create significant doubt of any claims of vaccine related injury." Resp't's Ex. A at 6.

Additionally, Dr. Gibbons noted Petitioner had a long history of anxiety and the medications prescribed for her anxiety also "could easily explain the constellation of symptoms that are reported in this case." Resp't's Ex. A at 5–6.

IV. Applicable Legal Standards

To receive compensation under the Vaccine Act, a petitioner must demonstrate either that: (1) the petitioner suffered a "Table injury" by receiving a covered vaccine and subsequently developing a listed injury within the time frame prescribed by the Vaccine Injury Table set forth at § 14, as modified by 42 C.F.R. § 100.3; or (2) that petitioner suffered an "off-Table injury," one not listed on the Table, as a result of his receiving a covered vaccine. *See* § 11(c)(1)(C); *Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1319–20 (Fed. Cir. 2006). Petitioner does not allege a Table injury in this case; thus, she must prove that her injury was caused-in-fact by a Table vaccine.

To establish causation-in-fact, a petitioner must demonstrate by a preponderance of the evidence that the vaccine was the cause of the injury. § 13(a)(1)(A). A petitioner is required to prove that the vaccine was "not only a but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321–22 (quoting *Shyface v. Sec'y of Health & Hum. Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)).

In the seminal case of *Althen v. Sec'y of the Dept. of Health & Hum. Servs*, the Federal Circuit set forth a three-pronged test used to determine whether a petitioner has established a causal link between a vaccine and the claimed injury. *See* 418 F.3d 1274, 1278–79 (Fed. Cir. 2005). The *Althen* test requires petitioners to set forth: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Id.* at 1278. To establish entitlement to compensation under the Program, a petitioner is required to establish each of the three prongs of *Althen* by a preponderance of the evidence. *Id.* "[C]lose calls regarding causation are resolved in favor of injured claimants." *Id.* at 1280. Further, evidence used to satisfy one prong of the test may overlap to satisfy another prong. *Capizzano*, 440 F.3d at 1326.

Under the first prong of *Althen*, a petitioner must offer a scientific or medical theory that answers in the affirmative the question: "can the vaccine[] at issue cause the type of injury alleged?" *Pafford v. Sec'y of Health & Hum. Servs.*, No. 01-0165V, 2004 WL 1717359, at *4 (Fed. Cl. Spec. Mstr. July 16, 2004), *mot. for rev. den'd*, 64 Fed. Cl. 19 (2005), *aff'd*, 451 F.3d 1352 (Fed. Cir. 2006). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Hum. Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such theory must only be "legally probable, not medically or scientifically certain." *Id.* at 548–49. Petitioners are not required to identify "specific biological mechanisms" to establish causation, nor are they required to present "epidemiologic studies, rechallenge[] the

presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities." *Capizzano*, 440 F.3d at 1325 (quoting *Althen*, 418 F.3d at 1280). Scientific and "objective confirmation" of the medical theory with additional medical documentation is unnecessary. *Althen*, 418 F.3d at 1278–81; *see also Moberly*, 592 F.3d at 1322. However, as the Federal Circuit has made clear, "simply identifying a 'plausible' theory of causation is insufficient for a petitioner to meet her burden of proof." *LaLonde v. Sec'y of Health & Hum. Servs.*, 746 F.3d 1334, 1339 (Fed. Cir. 2014) (citing *Moberly*, 592 F.3d at 1322). Indeed, the Federal Circuit has "consistently rejected theories that the vaccine only 'likely caused' the injury and reiterated that a 'plausible' or 'possible' causal theory does not satisfy the standard." *Boatmon v. Sec'y of Health & Hum. Servs.*, 941 F.3d 1351, 1360 (Fed. Cir. 2019) (citing *Moberly*, 592 F.3d at 1322 and *LaLonde*, 746 F.3d at 1339). Rather, "[a] petitioner must provide a reputable medical or scientific explanation that pertains specifically to the petitioner's case." *Moberly*, 592 F.3d at 1322. In general, "the statutory standard of preponderance of the evidence requires a petitioner to demonstrate that the vaccine more likely than not caused the condition alleged." *LaLonde,* 746 F.3d at 1339.

Furthermore, establishing a sound and reliable medical theory connecting the vaccine to the injury often requires a petitioner to present expert testimony in support of his claim. *Lampe v. Sec'y of Health & Hum. Servs.*, 219 F.3d 1357,1361 (Fed. Cir. 2000). The Supreme Court's opinion in *Daubert v. Merrell Dow Pharmaceuticals, Inc.* requires that courts determine the reliability of an expert opinion before it may be considered as evidence. 509 U.S. 579 (1993). However, in the Vaccine Program, the *Daubert* factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Hum. Servs.*, 94 Fed. Cl. 53, 66–67 (2010) ("[U]niquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted."); *see also Cedillo v. Sec'y of Health & Hum. Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec'y of Health & Hum. Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999)). Under *Daubert*, the

> factors for analyzing the reliability of testimony are: (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

Terran, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592–95).

The *Daubert* factors are "meant to be helpful, not definitive." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 151 (1999). The factors do not "constitute 'a definitive checklist or test'" and may be applied differently depending on the facts of a particular case. *Id.* at 150 (quoting *Daubert*, 509 U.S. at 593).

"In short, the requirement that an expert's testimony pertain to 'scientific knowledge' establishes a standard of evidentiary reliability." *Daubert*, 509 U.S. at 590 (citation omitted). Thus, for Vaccine Act claims, a "special master is entitled to require some indicia of reliability to support

the assertion of the expert witness." *Moberly*, 592 F.3d at 1324. Nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder v. Sec'y of Health & Hum. Servs.*, 88 Fed. Cl. 706, 743 (2009) (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)); *see also D'Tiole v. Sec'y of Health & Hum. Servs.*, No. 15-085V, 2016 WL 7664475, at *24 (Fed. Cl. Spec. Mstr. Nov. 28, 2016) (stating that the Vaccine Act "require[s] a chain of reliable propositions supporting [a] petitioner's theory").

Under the second prong of *Althen*, a petitioner must prove that the vaccine actually did cause the alleged injury in a particular case. *See Pafford*, 2004 WL 1717359, at *4; *Althen*, 418 F.3d at 1279. The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Hum. Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). A petitioner does not meet this obligation by showing only a temporal association between the vaccination and the injury; instead, the petitioner "must explain *how* and *why* the injury occurred." *Pafford*, 2004 WL 1717359, at *4 (emphasis in original). The special master in *Pafford* noted petitioners "must prove [] both that her vaccinations were a substantial factor in causing the illness . . . and that the harm would not have occurred in the absence of the vaccination." *Id.* (citing *Shyface*, 165 F.3d at 1352). A reputable medical or scientific explanation must support this logical sequence of cause and effect. *Hodges v. Sec'y of Health & Hum. Servs.*, 9 F.3d 958, 961 (Fed Cir. 1993) (citation omitted). Nevertheless, "[r]equiring epidemiologic studies . . . or general acceptance in the scientific or medical communities . . . impermissibly raises a claimant's burden under the Vaccine Act and hinders the system created by Congress." *Capizzano*, 440 F.3d at 1325–26. "[C]lose calls regarding causation are resolved in favor of injured claimants." *Althen*, 418 F.3d at 1280.

In Program cases, contemporaneous medical records and the opinions of treating physicians are favored. *Capizzano*, 440 F.3d at 1326 (citing *Althen*, 418 F.3d at 1280). Indeed, when reviewing the record, a special master must consider the opinions of treating physicians. *Capizzano*, 440 F.3d at 1326. This is because "treating physicians are likely to be in the best position to determine whether 'a logical sequence of cause-and-effect show[s] that the vaccination was the reason for the injury.'" *Id.* In addition, "[m]edical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). However, there is no "presumption that medical records are accurate and complete as to all of the patient's physical conditions." *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021) (finding that a special master must consider the context of a medical encounter before concluding that it constitutes evidence regarding the absence of a condition). While a special master must consider these opinions and records, they are not "binding on the special master or court." § 13(b)(1). Rather, when "evaluating the weight to be afforded to any such . . . [evidence], the special master . . . shall consider the entire record." *Id.*

In determining the accuracy and completeness of medical records, special masters will consider various explanations for inconsistencies between contemporaneously created medical

records and later given testimony. The Court of Federal Claims has identified four such explanations for explaining inconsistencies: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Hum. Servs.*, 110 Fed. Cl. 184, 203 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014).

To satisfy the third *Althen* prong, a petitioner must establish a "proximate temporal relationship" between the vaccination and the alleged injury. *Althen*, 418 F.3d at 1281. This "requires preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." *de Bazan v. Sec'y of Health & Hum. Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). Typically, "a petitioner's failure to satisfy the proximate temporal relationship prong is due to the fact that onset was too late after the administration of a vaccine for the vaccine to be the cause." *Id.* However, "cases in which onset is too soon" also fail this prong; "in either case, the temporal relationship is not such that it is medically acceptable to conclude that the vaccination and the injury are causally linked." *Id.*; *see also Locane v. Sec'y of Health & Hum. Servs.*, 685 F.3d 1375, 1381 (Fed. Cir. 2012) ("[If] the illness was present before the vaccine was administered, logically, the vaccine could not have caused the illness.").

Although a temporal association alone is insufficient to establish causation, under the third prong of *Althen*, a petitioner must also show that the timing of the injury fits with the causal theory. *See Althen*, 418 F.3d at 1278. The special master cannot infer causation from temporal proximity alone. *See Thibaudeau v. Sec'y of Health & Hum. Servs.*, 24 Cl. Ct. 400, 403–04 (1991); *see also Grant*, 956 F.2d at 1148 ("[T]he inoculation is not the cause of every event that occurs within the ten[-]day period . . . [w]ithout more, this proximate temporal relationship will not support a finding of causation." (quoting *Hasler v. United States*, 718 F.2d 202, 205 (6th Cir. 1983))).

A petitioner who satisfies all three prongs of the *Althen* test has established a prima facie showing of causation. *Hammitt v. Sec'y of Health & Hum. Servs*., 98 Fed. Cl. 719, 726 (2011). A petitioner who demonstrates by a preponderance of the evidence that he suffered an injury caused by vaccination is entitled to compensation unless the respondent can demonstrate by a preponderance of the evidence that the injury was caused by factors unrelated to the vaccination. *See Althen*, 418 F.3d at 1278; *Knudsen*, 35 F.3d at 547. In such a case, the government must not merely prove the existence of an alternative cause, but that such an alternative actually caused the injury. *Knudsen*, 35 F.3d at 549. Consequently, when and if the petitioner establishes a prima facie case, the burden then shifts to the government to prove that an alternative cause, unrelated to the administration of the vaccine, was the "sole substantial factor" in causing the alleged injury. *See de Bazan v. Sec'y of Health & Hum. Servs.*, 539 F.3d 1347, 1354 (Fed. Cir. 2008); *see also Hammitt*, 98 Fed. Cl. at 726 (explaining that the respondent's burden is to show that the "factor unrelated" was the "sole substantial factor" in causing the injury). Additionally, a factor unrelated "may not include 'any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness or condition.'" § 13(a)(2); *see also Doe v. Sec'y of Health & Hum. Servs.*, 601 F.3d 1349 (Fed. Cir. 2010) (stating that an idiopathic diagnosis cannot be a "factor unrelated," as it is idiopathic).

V. Discussion

A. Diagnosis

As Federal Circuit precedent establishes, in certain cases it is appropriate to determine the nature of an injury before engaging in the *Althen* analysis. *See Hibbard v. Sec'y of Health & Hum. Servs.*, 698 F.3d 1358, 1364-65 (Fed. Cir. 2012); *Lombardi v. Sec'y of Health & Hum. Servs.*, 656 F.3d 1343, 1353 (Fed. Cir. 2011); *Broekelschen v. Sec'y of Health & Hum. Servs.*, 618 F.3d 1339, 1346 (Fed. Cir. 2010) (finding that in a case where the injury itself is in dispute, it is appropriate for the special master to "first determine which injury was best supported by the evidence presented in the record before applying the *Althen* test so that the special master could subsequently determine causation relative to the injury."). Here, the parties dispute diagnosis, and so it is appropriate to first resolve that issue.

I find that Petitioner has presented preponderant evidence that she suffers from SFN for the purpose of her causation-in-fact claim. Following her 2015 vaccination, Petitioner experienced intermittent muscle twitching, numbness and tingling, paresthesias, muscle spasms, and weakness throughout her body. The spasms were mainly in her thighs, and the left side was worse than the right. GBS, MS, and ALS were ruled out by neurological specialists. TM and CIDP were considered, but not diagnosed. Petitioner's EMG/NCS, EEG, MRI, and serologic workup, performed in 2016, were all normal. Petitioner sought further evaluation in 2017 from Dr. Mhoon at Duke Neurology. Neurologic examination revealed "reduced temperature and pinprick sensation in the feet bilaterally." Pet'r's Ex. 5 at 12. Based on her history and examination, Dr. Mhoon suspected SFN and ordered a skin biopsy. The skin biopsy result showed "significantly reduced [e]pidermal [n]erve [f]iber [d]ensity, consistent with [SFN]." *Id.* at 15. Neurologist Dr. Washburn subsequently noted the SFN diagnosis and agreed a diagnosis of SFN may explain Petitioner's "random/twitches/cramps/pains." Pet'r's Ex. 7 at 13.

Dr. Gibbons disputed the accuracy of the skin biopsy result. However, none of Petitioner's treating providers doubted the result in subsequent appointments. And although Dr. Mhoon noted SFN does not explain all of her symptoms, he did not disregard the biopsy result or make any other diagnosis. Dr. Gibbons also opined SFN does not explain all of Petitioner's symptoms. However, based on his own discussion of relevant symptoms, SFN does explain some of Petitioner's symptoms. According to the medical literature filed, including an article authored by Dr. Gibbons, symptoms of SFN include the sensory disturbances Petitioner described. A near normal examination is also typical of SFN, although there may be decreased pinprick and thermal sensations, which Petitioner exhibited. The presence of an additional undiagnosed condition and/or symptoms consistent with her comorbidities, such as anxiety and joint disease, does not exclude a SFN diagnosis. Moreover, Dr. Gibbons conceded that if the skin biopsy result is correct, and there is no evidence to suggest otherwise, Petitioner would suffer from a mild case of SFN. Indeed Dr. Gibbons' own article stated that symptoms of SFN can vary in severity. Importantly, the severity of the injury (how mild or serious the injury is) does not dictate the establishment of an injury's existence.[40]

[40] The only severity requirement is that the injury persists for at least six months. *See* § 11(a)(1). That is not an issue here.

I find the arguments against a SFN diagnosis unpersuasive to overcome the opinion of Petitioner's treaters in this case. After consideration of the medical record and the expert analysis, I find that Petitioner presented preponderant evidence that she suffers from SFN.

B. *Althen* Prong One – Medical Theory

I find preponderant evidence that Petitioner has met her burden under *Althen* prong one. Petitioner's expert, Dr. Steinman, posited a reliable medical theory showing that the flu vaccine can cause SFN. Dr. Steinman opined that the 2015 flu vaccine triggered an autoimmune response to the α3 nicotinic AChR via molecular mimicry, resulting in SFN. Dr. Steinman based his theory, in part, on the notion of "recall response."

Dr. Steinman proposed that components of the 2015-2016 flu vaccine can cross react with the α3 nicotinic AChR, which, according to McKeon et al., is associated with SFN. Conducting a BLAST search, Dr. Steinman compared the sequence of α3 AChR, with the sequence of components of the flu vaccine, namely nucleocapsid and hemagglutinin. The sequence RESRNPGNAE had five of 10 identical amino acids between the nucleocapsid protein and α3AChR. The sequence DKAKIDLVLIG had seven of 11 identical amino acids between the hemagglutinin component and α3 AChR. Based on the Gautam et al. articles, which found "[five] of 12 amino acids, not even consecutive amino acids, was sufficient to trigger [EAE]," Dr. Steinman opined that the stretch of the sequence homologies found in this case was sufficient to trigger clinically relevant neuroinflammation. Pet'r's Ex. 13 at 11.

Dr. Gibbons did not dispute the method used or that the homologies found by Dr. Steinman were sufficient to show a degree of molecular mimicry capable of triggering neuroinflammation. Curiously, he waited until his final supplemental expert report to opine that α3 AChR is not associated with SFN, even though Dr. Steinman proposed this in his first expert report. Moreover, Dr. Gibbons did not provide support for his assertion.

In Dr. Steinman's final expert report, he introduced a recall response theory and presented literature to show "how repeated immunization with a molecular mimic could finally result in a pathologic response to the molecular mimic." Pet'r's Ex. 36 at 5. He explained how an autoimmune disease from a cross-reaction immune response is more likely to occur when there have been multiple exposures to the mimic. Dr. Steinman proposed that repeated immunization of the flu vaccine could result in a recall response and result in neuropathy. Dr. Gibbons responded that Dr. Steinman's support for a recall response is based on MS and that MS and SFN are not related. I agree with Dr. Gibbons that Dr. Steinman did not explain how a "hypersensitivity reaction in response to administration of molecular mimic myelin basic protein in patients with [MS]" is analogous to a flu vaccination causing SFN. Resp't's Ex. E at 2. However, this is not fatal to Petitioner's claim as Dr. Steinman's supporting literature provides preponderant evidence that the flu vaccine can cause SFN via molecular mimicry sans a recall response.

Moreover, in the Vaccine Program, molecular mimicry has been accepted as a sound and reliable theory in many demyelinating conditions, including those conditions that cause damage to unmyelinated small neurons, which is what occurs in SFN. *See, e.g.*, *Barone v. Sec'y of Health &*

Hum. Servs., No. 11-707V, 2014 WL 6834557, at *8–9 (Fed. Cl. Spec. Mstr. Nov. 12, 2014) (noting molecular mimicry "has been accepted in other Program cases as a reliable medical explanation for how various autoimmune conditions could develop after the receipt of different kinds of vaccinations"); *E.M. v. Sec'y of Health & Hum. Servs.*, No. 14-753V, 2021 WL 3477837, at *36–39 (Fed. Cl. Spec. Mstr. July 9, 2021) (finding molecular mimicry a sound and reliable theory for how the flu vaccine can cause SFN); *Quirino v. Sec'y of Health & Hum. Servs.*, No. 17-989V, 2023 WL 9229145, at *19–21 (Fed. Cl. Spec. Mstr. Dec. 18, 2023) (finding molecular mimicry a sound and reliable theory for how the hepatitis B vaccine can cause SFN).

Although, the decisions of other special masters are not binding, I agree generally with the reasoning of my colleagues here. *See Boatmon*, 941 F.3d at 1358; *Hanlon v. Sec'y of Health & Hum. Servs.*, 40 Fed. Cl. 625, 630 (1998), *aff'd*, 191 F.3d 1344 (Fed. Cir. 1999).

Petitioner has provided a scientific or medical theory describing the flu vaccine's role in the development of SFN via molecular mimicry. As a result, Petitioner has met her burden by a preponderance of the evidence that the flu vaccine can cause SFN. Accordingly, I find Petitioner has satisfied prong one of *Althen.*

C. *Althen* Prong Two – Actual Causation

There are three reasons why I find preponderant evidence of a logical sequence of cause and effect establishing that the flu vaccine administered to Petitioner on October 5, 2015, was the cause of her SFN. First, as described above, I found Petitioner preponderantly established a diagnosis of SFN, and Petitioner proffered a sound and reliable mechanism of vaccine causation.

Petitioner's expert provided a medical theory showing that the components of Petitioner's October 5, 2015 flu vaccine mimicked the α3 AChR associated with SFN. He reasoned that this response likely triggered the immune cross-reaction to α3 AChR, resulting in Petitioner's SFN. I accept Dr. Steinman's theory regarding how the flu vaccine could have triggered Petitioner's SFN, and I find that his theory fits the facts of this case sans a recall response. Petitioner's symptom presentation was consistent with SFN as described above. Petitioner received the flu vaccine on October 5, 2015. She presented to the ED on October 15, 2015, with numbness and tingling. Paresthesias was one of the diagnoses. She returned to the ED on October 19, 2015, where she reported that she had a flu shot two weeks prior and "later that night after receiving the vaccine, she felt chills, generalized upper respiratory congestion[,] and generally fatigued." Pet'r's Ex. 2 at 37. "[Six] days ago[,] she began to experience waves of bilateral head to toe numbness and paresthesias which would wax and wane and spontaneously resolved." *Id.* "Over the last several days [Petitioner] [] had continued episodes of numbness" and reported "proximal muscle twitching which was bilateral with intermittent random fasciculations and generalized proximal muscle fatigue. This has been intermittent, waxing and waning over the weekend until this morning where she was walking at Lowe's and seemed to have more difficulty." *Id.* "Reaction to [flu] immunization" was listed in diagnoses. *Id.* at 42. Petitioner was eventually diagnosed with SFN by Dr. Mhoon in 2017 following neurologic examination and a skin biopsy consistent with SFN.

Relevant to her clinical presentation following her October 5, 2015 flu vaccine, is her clinical presentations from prior flu vaccines. In 2012, Petitioner received a flu vaccine and one

week later, developed numbness and tingling in her feet, lower legs, and hands. Her neurologist, Dr. Borresen, "advised [Petitioner] to avoid the flu shots since she has had side effects of paresthesias." Pet'r's Ex. 12 at 8. Petitioner also reported that she had a similar reaction to the flu shot two years prior. A review of the medical records does not show a flu shot in 2010. Petitioner did receive a flu shot in 2009. And on October 27, 2009, Petitioner presented to MNA for left-sided tingling that started after receiving a flu shot. However, medical records indicate her flu shot in 2009 was on November 2, 2009, which would be six days after the appointment where she reported the reaction. Nonetheless, Dr. Borresen noted Petitioner's symptoms "could be a minor reaction to the flu shot." *Id.* at 133. Thus, her treating neurologist documented prior reactions and cautioned her about future flu vaccines. These separate instances of reactions to flu vaccines show a predisposition to an adverse reaction.

Second, Petitioner's treating physicians related her condition back to the flu vaccine. *See, e.g.*, Pet'r's Ex. 7 at 125 (Dr. Borresen writing that Petitioner "may have some minor reaction to the flu shot"); Pet'r's Ex. 5 at 12 (Dr. Mhoon writing that Petitioner's SFN "may be related to postvaccination small fiber neuritis"), 53 (Dr. Mhoon noting Petitioner's SFN may be related to her vaccination or prediabetes); Pet'r's Ex. 2 at 43 (Dr. Bowen writing "[r]eaction to [flu] immunization" as one of the diagnoses.); Pet'r's Ex. 1 at 760 (P.A. Phillips noting that Petitioner "did have her flu shot when she was at our office on [October 5, 2015]" in response to Petitioner's presenting symptoms).

Additionally, Petitioner consistently related her symptoms back to the flu vaccination. *See, e.g.*, Pet'r's Ex. 2 at 37 (Petitioner reporting on October 19, 2015, that she had a flu shot two weeks prior and "later that night after receiving the vaccine[] she felt chills, generalized upper respiratory congestion[,] and generally fatigued;" that prior to that, she has had no further issues from that until her recent flu shot [two] weeks ago;" and that she had a similar presentation with her paresthesias from a flu shot five years ago); Pet'r's Ex. 7 at 139 (On October 20, 2015, Petitioner felt "strongly that her symptoms [were]. . . sequala of a recent flu vaccine" two weeks ago.); Pet'r's Ex. 1 at 760 (Petitioner remembering similar, but milder, symptoms after her flu shot in 2010 and 2012), 132 (P.A. Phillip noting Petitioner was "convinced she ha[d] a mild case of GBS following the flu vaccine"); Pet'r's Ex. 4 at 2 (Petitioner reporting to physical therapy on November 30, 2015, that she began experiencing muscle spasms, weakness, and tingling in her bilateral upper and lower extremities about one week after her flu vaccination); Pet'r's Ex. 6 at 26 (Petitioner explaining to Dr. Rao on January 4, 2016, that she got a flu shot on October 5, 2015, then around October 13, 2015, she developed numbness and tingling of the arms and legs as well as muscle spasms and weakness).

The third reason for finding that Petitioner has met her burden to prove that the vaccine she received actually did cause her SFN is that I do not find preponderant evidence of an alternative cause. Potential alternative causes can undermine Petitioner's prima facia claim when present in the medical record, and Petitioner must provide preponderant evidence of her alleged condition despite differential diagnoses in those instances. Respondent contends a combination of pre-diabetes and anxiety were the cause of her symptoms. While I consider Respondent's rebuttal regarding the alternative causes and differential diagnoses, I find it unpersuasive as discussed more in depth in the alternative cause section below.

Overall, Petitioner has established by a preponderance of the evidence that the flu vaccine administered on October 5, 2015, caused her to develop SFN. *See Capizzano*, 440 F.3d at 1326; *see also Althen*, 418 F.3d at 1280 (finding that "close calls regarding causation are resolved in favor of injured claimants."). Therefore, Petitioner has satisfied prong two of *Althen.*

D. *Althen* Prong Three – Temporal Relationship

Dr. Steinman opined Petitioner's onset of SFN began about six days after her October 5, 2015 flu vaccination. Dr. Gibbons found "it difficult to ascertain a date of onset of symptoms suggestive of neuropathy given the frequency with which symptoms of numbness and tingling have been reported from 2005-2013 prior to the onset of the alleged injury." Resp't's Ex. E at 1. Petitioner received the flu vaccine on October 5, 2015. She presented to the ED ten days later with numbness and tingling. Four days later, she returned to the ED and reported that "she underwent a flu shot [two] weeks ago, and later that night after receiving the vaccine[] she felt chills, generalized upper respiratory congestion[,] and generally fatigued. [Six] days ago[,] she began to experience waves of bilateral head to toe numbness and paresthesias which would wax and wane and spontaneously resolved." Pet'r's Ex. 2 at 37. Although Petitioner was not diagnosed until 2017, the literature filed by both Dr. Steinman and Dr. Gibbons support that Petitioner's symptoms in the days following her vaccination represent the onset of SFN. Therefore, I find onset to be approximately one week post vaccination.

Having determined onset to be approximately one week, the next question is whether there is "preponderant proof that the onset of symptoms occurred within a time frame for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." *de Bazan*, 539 F.3d at 1352.

Dr. Steinman opined six days is appropriate given the purported autoimmune mechanism of molecular mimicry. He relied on Schonberger et al. to show a six-day onset of SFN is consistent with an increase in inflammatory neuropathy after flu vaccination. While Schonberger et al. found, on average, an onset between two and three weeks, it also showed how molecular mimicry can induce an autoimmune response in as little as one week. *See* Pet'r's Ex. 29 at 9 fig. 5. However, Dr. Steinman did not explain how the proposed onset is consistent with a recall response. Dr. Gibbons did not dispute that the immune system can elicit a response six days or one week after vaccination.

Moreover, in comparing the pathophysiology of SFN to GBS,[41] this temporal association is also consistent with the onset period of three to 42 days as set forth in the Vaccine Injury Table for GBS following flu vaccination. 42 C.F.R. § 100.3(a)(XIV)(D).

Therefore, I find the temporal association is appropriate given the mechanism of molecular mimicry and Petitioner has satisfied the third *Althen* prong.

[41] *See Coons v. Sec'y of Health & Hum. Servs.*, No. 20-1067V, 2024 WL 1741619, at *23 (Fed. Cl. Spec. Mstr. Mar. 29, 2024) (comparing the pathophysiology of SFN to GBS and citing other Program cases that found the same).

E. Alternative Causation

Because I conclude that Petitioner established a prima facie case of causation, Petitioner is entitled to compensation unless Respondent can put forth preponderant evidence "that Petitioner's injury was in fact caused by factors unrelated to the vaccine." *Whitecotton v. Sec'y of Health & Hum. Servs.*, 17 F.3d 374, 376 (Fed. Cir. 1994), *rev'd on other grounds sub nom.*, *Shalala v. Whitecotton*, 514 U.S. 268 (1995); *see also Walther v. Sec'y of Health & Hum. Servs.*, 485 F.3d 1146, 1151 (Fed. Cir. 2007).

Dr. Gibbons opined that even if Petitioner has SFN, the "the most plausible explanation . . . is pre-diabetes." Resp't's Ex. D at 2. Dr. Mhoon also noted Petitioner's SFN may be related to her vaccination or pre-diabetes. While Petitioner was diagnosed with pre-diabetes in 2012, which was confirmed in follow-up visits in 2013 and 2014, SFN was not diagnosed until after her October 5, 2015 flu vaccination. Moreover, Respondent did not present preponderant evidence that Petitioner's SFN was caused by pre-diabetes by way of a mechanistic theory, only that pre-diabetes is a common cause of SFN and predisposes individuals to SFN.

Additionally, Dr. Gibbons noted Petitioner had a long history of anxiety, and the medications prescribed for her anxiety "could easily explain the constellation of symptoms that are reported in this case." Resp't's Ex. A at 5–6. Similarly, Dr. Washburn noted the possibility of Petitioner's mental health impacting her unexplained physical symptoms. And while Dr. Borresen wrote, Petitioner "may have some minor reaction to the flu shot," he added that Petitioner "has a tendency to somatization and worry which is most likely going on." Pet'r's Ex. 7 at 125. However, these opinions are not to the preponderant standard and are unpersuasive in the presence of a skin biopsy (consistent with SFN) and neurologic examination (positive for reduced temperature and pinprick sensation) confirming her symptomology.

I find Respondent failed to provide persuasive evidence that Petitioner's SFN was caused by a source other than vaccination. Thus, Respondent did not prove by a preponderance of evidence that Petitioner's injury is "due to factors unrelated to the administration of the vaccine." § 13(a)(1)(B).

VI. Conclusion

After a careful review of the record, I find Petitioner has proved by preponderant evidence that her SFN was caused-in-fact by her October 5, 2015 flu vaccination. Accordingly, Petitioner is entitled to compensation. A separate damages order will issue.

IT IS SO ORDERED.

s/Herbrina D. S. Young
Herbrina D. S. Young
Special Master